PRECISION PIN USER MANUAL

NON STERILE PRODUCTS

PRODUCTS

Part Number	Description
000603-02	Precision Pin, 120mm length, 3.2 mm diameter
000604-02	Precision Pin, 75mm length, 3.2 mm diameter
000613-02	Precision Stop Pin, 50mm length, 3.2 mm diameter
000617-10	Universal Threaded Pin 100 mm length, 3.0 mm diameter
000617-15	Universal Threaded Pin 150 mm length, 3.0 mm diameter
009096-02	Fluted Pin, 89 mm length, 3.2 mm diameter

PRODUCT DESCRIPTION

All Pins listed above are supplied as single use non-sterile. They must be cleaned and sterilized according to the guidelines below.

The precision pins, fluted pins and universal pins are manual instrument that are used as drill bit/smooth pin replacements to secure cutting blocks to bone during a total and uni knee arthroplasty.

MATERIAL SPECIFICATIONS

316L stainless steel (ASTM F138-08)

INTENDED USE/INDICATIONS FOR USE

The precision pins, fluted pins and universal pins are intended to be used in TKR/Uni knee replacement to stabilize and hold cutting blocks to bone.

INSTRUCTIONS

Precision Pin

1. By hand, pre-load the pin into the cutting block.
2. Push the pin through the hole, so the pin tip pierces the near cortex of the bone.
3. Place the pin collet driver of the drill over the top of the pin and then drill the pin into place. Slowly advance the pin into bone to avoid over-drilling.

4. If available, a headless pin driver can also be used for insertion of the pin.
5. Ensure that, upon removal of the pin, the drill is place in reverse so the pin will not continue through the bone and cause injury to surrounding soft tissues.
6. If the any of the pins are bent or scored during use, replace the pin immediately.

CONTRAINDICATIONS

1. Foreign body sensitivity, known or suspected allergies to implant and/or pin materials.
2. Active sepsis or infection.
3. Conditions that tend to limit the patient's ability or willingness to restrict activities or to follow directions during the healing and rehabilitation period.

WARNINGS

1. The pins may be extremely sharp. Improper handling of the pins may result in injury.
2. Patient should be advised that product materials may cause allergic reactions, including without limitation foreign body reaction, tissue irritation and inflammation, or other allergic reactions. Where material sensitivity is suspected, appropriate test should be made and sensitivity ruled out prior to use.
3. Additional warnings include those applicable to any surgical procedure. In general, careful attention must be paid to asepsis and avoidance to anatomical hazards.
4. Do not apply side or bending loads. Application of side or bending loads may result in breakage of the pins and risk of tissue damage or debris.
5. Do not over-drill the stop pin, as it will result in breakage of the pin, stripping of bone or compression of bone.
6. Beyond a single use, the precision, fluted and universal pins integrity could be compromised and cause breakage or incarceration in cutting block.

ADVERSE EVENT WARNINGS (please note warnings below)

Pin holes alter the stress distribution and decrease the breaking strength of any bone and may cause stress fracture.
To minimize the risk of stress fractures, the distal femoral metaphysis and pin placement from lateral to medial is preferred.

Avoid placing the Pins into bone sections which are subject to high tensile or torsional stress moments in order to minimize the risk of stress fracture.
Transcortical pin fixation is most detrimental to bone strength and may be associated with increased risk of bone necrosis.
Pin insertion generates heat. Excessive heat generation may result in bone necrosis. Bone necrosis potentially delays the pin hole healing process and increases the risk of stress fractures. Ensure low drilling speed in order to avoid excessive heat generation. External irrigation should be applied, if possible.
Depending on bone stock, pre-drilling with a drill diameter smaller than the intended pin diameter may be indicated.

PRECAUTIONS

1. Prior to use, remove all protective packaging and tip protector, if applicable.
2. Inspect the pins prior to use to ensure they are in good physical condition and functions properly. Do not use the pins if there is any loose, broken or misaligned part.
3. Exercise care in the use of the pins to minimize side or bending loads.
4. To avoid damage or breakage during use of the pins, do not use excessive force on the pins.
5. To prevent damage or breakage of the pins, avoid contact with other surgical pins during use.
6. Inspect the pins after use to ensure the pins have not been damaged.
7. The pins are designed for use by surgeons experienced in the appropriate specialized procedures. It is the responsibility of the surgeon to become familiar with the proper techniques for use of the pins.

ADVERSE EFFECTS

1. Deep and superficial infections.
2. Allergies, tissue irritation and inflammation, and other reactions to materials.
3. Transient local fluid accumulation or sinus formation, arthritis pain or deformity and stiffness.
4. Bone fracture.

CLEANING AND STERILIZATION GUIDELINES

CLEANING

1. Follow universal precautions for protective apparel when handling and cleaning non-sterile products.
2. Place the instrument in a basin with distilled water.
   NOTE: Saline solution is not recommended, as it has a corrosive effect on certain metals.
3. The instrument should be cleaned using a neutral pH cleaning solution and a non-abrasive brush.
4. Rinse the instrument under running water followed by a rinse in distilled water.
5. Dry the instrument completely using a clean, lint-free towel.

STEAM STERILIZATION

WARNINGS

1. Do not use EtO or gamma sterilization.
2. Do not use disinfecting solutions to sterilize the instruments.

Prepare instruments such that all surfaces have direct contact with steam.

Method	Cycle	Minimum Temperature	Minimum Exposure	Minimum Dry Cycle
Steam (wrapped/unwrapped)	Pre-Vacuum	270°F (132°C)	4 minutes	8 minutes

For sterilization of instruments in a tray, consult guidelines provided with the specific sterilization tray.

CAUTION

Federal law (USA) restricts this instrument to sale, distribution, or use by or on the order of a licensed healthcare practitioner.

DISCLAIMER

OPERATIV MAKES NO WARRANTY TO YOU AND HEREBY EXPRESSLY DISCLAIMS ALL WARRANTIES, WHETHER EXPRESS OR IMPLIED, WITH RESPECT TO THE PINS, LISTED ABOVE, WHETHER ARISING BY COURSE OF DEALING OR PERFORMANCE, CUSTOM, USAGE IN THE TRADE OR PROFESSION OR OTHERWISE, INCLUDING BUT NOT LIMITED TO, WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE.

CONTACT INFORMATION

For more information or a product demonstration, contact your Operativ sales representative, or call 1-425-284-7262 in the United States.

Operativ
11321 NE 120th St.
Kirkland, WA 98034
www.Operativ.com
425-284-7262
Fax 425-968-7555

Rx ONLY